



American Bakers Association

Serving the Baking Industry Since 1897

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August 18, 2005

Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Citizen Petition to Amend the Food Definitions and Standards
of Identity for Bakery Products (21 C.F.R. Part 136) and to
Repeal the Food Definition and Standard of Identity and
Quality for Frozen Cherry Pie (21 C.F.R. Part 152)

Dear Sir/Madam:

Attached for filing is a Citizen Petition submitted on behalf of the members of the American Bakers Association ("ABA"), the national trade association representing the wholesale baking industry. ABA membership consists of bakers and bakery suppliers who together are responsible for the manufacture of approximately 80 percent of the baked goods sold in the United States. The instant Citizen Petition seeks to amend the food definitions and standards of identity for bakery products (21 C.F.R. Part 136) and to repeal the food definition and standard of identity and quality for frozen cherry pie (21 C.F.R. Part 152).

ABA previously submitted a Citizen Petition on these matters, on February 3, 1997. The attached petition is largely the same as the earlier petition but has been updated to reflect technical and policy developments that have occurred in the intervening eight years. Accordingly, ABA withdraws its 1997 petition, and requests the agency to file a copy of the attached petition instead.

Respectfully submitted,

Lee Sanders
Vice President
Regulatory & Technical Services

Paul C. Abenante
President & CEO

Attachments

2005 P-0332

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CITIZEN PETITION

**To Amend The Food Definitions and
Standards of Identity For Bakery Products
(21 C.F.R. Part 136)
And To Repeal The Food Definition and
Standard of Identity and Quality For
Frozen Cherry Pie (21 C.F.R. Part 152)**

The undersigned American Bakers Association ("ABA") submits this petition under Section 401 of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") and Section 130.5 of the Food and Drug Administration ("FDA") Regulations to request the Commissioner of Food and Drugs to:

1. Publish a proposed regulation to amend the definitions and standards of identity for bakery products in 21 C.F.R. Part 136 to simplify these standards in accordance with the Proposed Rule on Food Standards; General Principles and Food Standards Modernization published in 70 Fed. Reg. 29214 (May 20, 2005) and the Reinventing Government policy relating to food standards discussed in FDA's Advance Notice of Proposed Rulemaking published in 60 Fed. Reg. 67492 (December 29, 1995); and

A. Action Requested

1. ABA requests the Commissioner to publish a proposed regulation to revise Part 136 of the FDA regulations to read as follows:

PART 136 -- BAKERY PRODUCTS

§ 136.1 Bread, Rolls, and Buns.

(a) Bread, white bread, wheat bread, white wheat bread, rolls, white rolls, buns, and white buns are the foods produced by baking mixed leavened dough prepared from one or more farinaceous ingredients, one or more moistening ingredients, and one or more leavening agents, to which may be added one or more ingredients that do not change the basic identity or adversely affect the physical or nutritional characteristics of the food.

(b) All ingredients from which the food is fabricated shall be safe and suitable.

(c) The name of the food is "bread", "white bread", "wheat bread", "white wheat bread", "rolls", "white rolls", "buns", or "white buns", as applicable.

§ 136.2 Enriched Bread, Rolls, and Buns.

(a) Each of the foods enriched bread, enriched rolls, and enriched buns conforms to the definition and standard of identity in § 136.1.

(b) Each such food contains in each pound 1.8 milligrams of thiamine, 1.1 milligrams of riboflavin, 15 milligrams of niacin, 0.43 milligrams of folic acid, and 12.5 milligrams of iron.

(c) Each such food may contain added calcium in such quantity that the total calcium content is 600 milligrams per pound.

(d) The requirements of subsections (b) and (c) will be deemed to have been met if reasonable overages of the vitamins and minerals, within the limits of good manufacturing practice, are present to ensure that the required levels of the vitamins and minerals are

maintained throughout the expected shelf life of the food under customary conditions of distribution and storage.

(e) The name of the food is "enriched bread", "enriched white bread", "enriched rolls", "enriched white rolls", "enriched buns", or "enriched white buns", as applicable.

§ 136.3 Milk Bread, Rolls, and Buns.

(a) Each of the foods milk bread, milk rolls, and milk buns conforms to the definition and standard of identity in § 136.1.

(b) The only moistening ingredient permitted in the preparation of the dough is milk, or a combination of dairy products when in such a proportion that the weight of the nonfat milk solids is not more than 2.3 times and not less than 1.2 times the weight of the milk fat therein, with or without water, in a quantity that provides not less than 8.2 parts milk solids for each 100 parts by weight of flour.

(c) No buttermilk, buttermilk product, cheese whey, cheese whey product, or milk protein is used.

(d) The name of the food is "milk bread", "milk rolls", or "milk buns", as applicable.

(e) If the food meets the definition and standard of identity in § 136.2, the name of the food specified in subsection (d) of this section may be preceded by the word "enriched".

§ 136.4 Egg Bread, Rolls, and Buns.

(a) Each of the foods egg bread, egg rolls, and egg buns conforms to the definition and standard identity in § 136.1.

(b) The food contains not less than 2.56 percent by weight of whole egg solids. One medium-sized egg is equivalent to 0.41 ounce of whole egg solids.

(c) The name of the food is "egg bread", "egg rolls", or "egg buns", as applicable.

2. The Definition and Standard of Identity and Quality for Frozen Cherry Pie

The definition and standard of identity and quality for frozen cherry pie in Section 152.126 -- which comprises all of Part 152 of the FDA regulations -- was developed and promulgated in the 1960s and 1970s.⁷ Although it is denominated as a definition and standard of identity and quality, in fact the sole purpose of this provision was to establish a standard of quality. The essential elements are the requirements that the drained cherry content is not less than twenty-five percent of the weight of the pie and that not more than fifteen percent by count of the cherries in the pie are blemished.

ABA opposes any use of food standards to establish quality characteristics of food in general and frozen cherry pies in particular. Food quality should be left to the decisions of food manufacturers, in determining what type of food products to make available to the public, and food consumers, who must then determine whether they wish to spend more money to purchase products of higher quality or less money to purchase products of lower quality. Put simply, standardization of quality is not properly a function of government in a democratic society.

There is, and always will be, both lower quality and higher quality food available to American consumers. If FDA were to attempt to regulate the quality of all food products marketed in this country, it would be an endless and hopeless task. Quality is properly perceived by individual members of the public as they consume the products they purchase in retail stores. A product of unacceptably low quality will not long survive.

⁷ 32 Fed. Reg. 15116 (November 1, 1967), 36 Fed. Reg. 3364 (February 23, 1971), and 38 Fed. Reg. 15503 (June 13, 1973).

There is no basis whatever for singling out frozen cherry pies for a standard of identity, but not similarly standardizing frozen apple, peach, and other fruit pies. The same quality issues that could arise for frozen cherry pies would exist also for other frozen fruit pies.

Nor is there any basis for differentiating between frozen and non-frozen fruit pies. Both categories raise the same quality issues.

ABA does not believe that a common or usual name regulation of this type is justified. Fresh and frozen fruit pies other than frozen cherry pie have been sold in retail stores throughout the country without any evidence of public confusion during the entire time that frozen cherry pies have been subject to a rigid standard. ABA therefore urges FDA to publish a proposed regulation revoking the standard of identity for frozen cherry pie in Section 152.126 and deleting Part 152 from the Code of Federal Regulations.

C. Environmental Impact

This petition raises no environmental impact and is subject to a categorical exclusion under Section 25.24(b)(1) of the FDA regulations.

D. Economic Impact

ABA will submit an economic impact statement to FDA if requested. This petition will decrease rather than increase costs and prices, will increase productivity, increase competition, will have no impact on supplies of important materials, could increase employment, and will not effect energy supply or demand.

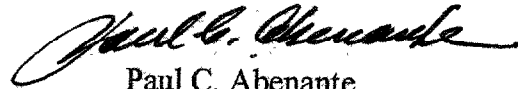
E. Certification

The undersigned certifies that, to his best knowledge and belief, this petition includes all information and views on which the petition relies, and that there are no data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,



Lee Sanders
Vice President
Regulatory & Technical Services



Paul C. Abenante
President & CEO

Attachment

(d) If the food meets the definition and standard of identity in § 136.2, the name of the food specified in subsection (c) of this section may be preceded by the word "enriched".

§ 136.5 Raisin Bread, Rolls, and Buns.

(a) Each of the foods raisin bread, raisin rolls, and raisin buns conforms to the definition and standard of identity in § 136.1.

(b) Not less than 50 parts by weight of seeded or seedless raisins are used for each 100 parts by weight of flour.

(c) Water extract of raisins may be used, but not to replace raisins.

(d) The name of the food is "raisin bread", "raisin rolls", or "raisin buns", as applicable.

(e) When the food contains not less than 2.56 percent by weight of whole egg solids, the words "and egg" may be added following the word "raisin" in the name of the food specified in subsection (d) of this section.

(f) If the food is made with enriched flour, the words "made with enriched flour" may be used as part of the name specified in subsection (d) of this section.

(g) If the food meets the definition and standard of identity in § 136.2, the name of the food specified in subsection (d) of this section may be preceded by the word "enriched".

§ 136.6 Whole Wheat Bread, Rolls, and Buns

(a) Each of the foods whole wheat bread, white whole wheat bread, whole grain bread, graham bread, whole wheat rolls, white whole wheat rolls, whole grain rolls, graham rolls, whole wheat buns, white whole wheat buns, whole grain buns, and graham buns conforms to the definition and standard of identity in § 136.1.

(b) The dough is made from whole wheat flour, brominated whole wheat flour, or a combination of these. No flour, brominated flour, or phosphated flour is used.

(c) The name of the food is "whole wheat bread", "white whole wheat bread", "whole grain bread", "graham bread", "whole wheat rolls", "white whole wheat rolls", "whole grain rolls", "graham rolls", "whole wheat buns", "white whole wheat buns", "whole grain buns", or "graham buns", as applicable.

2. ABA requests the Commissioner to publish a proposed regulation to revoke Part 152 of the FDA regulations in its entirety.

B. Statement of Grounds

ABA and its members have long been actively engaged in FDA's consideration of food standards modernization. As requested in the FDA Advance Notice of Proposed Rulemaking published in 60 Fed. Reg. 67492 (December 29, 1995), members of the baking industry submitted comments on the future utility of food standards for bakery products both through the American Bakers Association and through the Grocery Manufacturers of America. On February 3, 1997, ABA filed a Citizen Petition seeking nearly the same amendments as proposed in the instant petition.¹ Finally, concurrent with the filing of this petition, ABA submitted comments to FDA's Proposed Rule on Food Standards; General Principles and Food Standards Modernization ("Proposed General Principles"), published in 70 Fed. Reg. 29214 (May 20, 2005), of which this petition is a part. Copies of both sets of ABA comments are attached to this petition. To summarize, the baking industry supports the retention of definitions and standards of identity for bakery products, but urges FDA to amend the existing standards in order to limit them to two essential elements: the name (statement of identity) of the food and the essential characterizing properties of the food. All other elements should be deleted from

¹ The instant petition updates the 1997 petition to reflect technical and policy developments that have occurred in the intervening eight years. In its cover letter to this petition, ABA informs FDA that it withdraws its 1997 petition.

food standards. This petition would accomplish the objectives of the bakery industry as set forth in those comments.

1. The Definitions and Standards of Identity for Bakery Products

The ABA believes that it is important to have a uniform definition and standard of identity for bakery products that applies throughout the United States. There is, however, no need for a standard that goes beyond establishing the name (statement of identity) of the product and its essential characteristics, as FDA appears to recognize in its Proposed General Principles. Any provisions that extend beyond these two essential elements unnecessarily restrict modern food technology, deny consumers important new products in the marketplace, and thus harm the public interest.

The bakery products standards were initially developed and promulgated in the 1940s and 1950s.² Although they were revised to relax the recipe requirements in the 1970s,³ many unessential details were retained in the standards. It is now time to remove those unnecessary details and to reduce the bakery standards to the essential two elements: the name (statement of identity) and the essential characterizing properties of the food. This approach is consistent with and supportive of FDA's Proposed General Principles emphasizing simplicity and flexibility in food standards that are focused upon the essential characteristics of the food.

At the time the bakery products standards were promulgated as final regulations in 1952,⁴ FDA made explicit findings of fact that the standardized products were not intended to include all bakery products, but only those explicitly named in the standards. Thus, for example,

² 6 Fed. Reg. 2771 (June 7, 1941), 8 Fed. Reg. 10780 (August 3, 1943), 13 Fed. Reg. 6024 (October 14, 1948), 15 Fed. Reg. 5102 (August 8, 1950), and 17 Fed. Reg. 4453 (May 15, 1952).

³ 39 Fed. Reg. 32753 (September 11, 1974) and 41 Fed. Reg. 6242 (February 12, 1976).

⁴ 17 Fed. Reg. 4453 (May 15, 1952).

FDA explicitly declined to issue standards of identity for such products as high protein bakery products⁵ or various types of wheat bakery products.⁶ Entire classes of specialty bakery products, such as rye bread, were never proposed to be standardized and were not considered during the standard proceedings. ABA concurs in this approach. This proposal to reform the standards for bakery products is therefore intended only to establish revised and simplified standards for those products specifically named and described in the existing standards, and not the dozens of other bakery products commonly found in the marketplace.

It is unnecessary to review, in detail, all of the specific provisions that ABA proposes to delete from the existing standards. The following general description identifies the types of provisions that are proposed for revocation.

The definitions in current Section 136.3 serve no useful purposes. The words bread, rolls, and buns have well-established meanings. Some products that are shaped as bread, and that are intended to be used for that purpose, weigh less than one-half pound. Accordingly, these current definitions are unduly restrictive and contrary to Proposed General Principle number 9, which states that a food standard should allow for variations in the physical attributes of the food. The current Section 136.3 should be deleted.

Many of the bakery products standards continue to specify the various ingredients that must or may be used in making these products. ABA believes that all that is actually needed to characterize these products is to state that they are produced by baking mixed leavened dough prepared from one or more farinaceous ingredients, one or more moistening ingredients, and one or more leavening agents, to which may be added one or more ingredients that do not change the

⁵ Id. at 4456.

⁶ Id. at 4461.

basic identity or adversely effect the physical or nutritional characteristics of the food. Anything beyond this reduces innovation and harms the public interest.

It is important to specify the nutrients and levels that make a bakery product "enriched", the moistening ingredients that characterize milk bread, the amount of egg required for egg bread, the amount of raisins needed for raisin bread, and the amount whole wheat needed to make whole wheat bread. Beyond this, everything else is superfluous.

Because the revision of the bakery products standards provide an opportunity for clarification of current ambiguous provisions in the existing standards, ABA has included in this petition two provisions to improve the current standards. First, ABA has included a standard for enriched milk bread. Second, ABA has included standards for raisin bread made with enriched flour and for enriched raisin bread. All of these products have previously been marketed as non-standardized versions of standardized foods, with their own common or usual name, and FDA has acknowledged and allowed the use of enriched flour in these foods. There is no meaningful or justifiable distinction between non-standardized versions of these foods using enriched flour and their standardized, unenriched counterparts. Accordingly, the milk bread and raisin bread standards should be made flexible enough to include both enriched and unenriched versions of essentially the same foods.

For the foregoing reasons, ABA urges FDA to publish the proposed revision of the bakery products standards in Part 136. Revision of these standards could, indeed, properly be a prominent part of the initiative to reform United States food standards. By promptly publishing a proposal to revise the bakery products standards, FDA could set a welcome example for other food product categories.